# STATE OF CONNECTICUT
## DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

August 15, 2018

Mr. William Jennings, Administrator
Bridgeport Hospital
267 Grant Street
Bridgeport, CT 06610

Dear Mr. Jennings:

Unannounced visits were made to Bridgeport Hospital concluding on July 26, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for **September 6, 2018 at 2:00 PM** in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by **August 29, 2018** or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice. The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be

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advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Cheryl A. Davis, R.N., B.S.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

CAD/LH:jf

Complaint #23680

DATES OF VISIT: July 20, 24 and 26, 2018

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) and/or (4)(A) and/or (f) and/or (i) General (6)

1. *Based on a review of clinical records, review of facility policies, review of facility documentation, and interviews, during specimen processing and slide preparation on 7/10/17, the cytology prep technician erroneously loaded the slides incorrectly resulting in the switching of eight of the twelve specimens (five gynecological and seven urine specimens) and as a result, Patient #1 was erroneously informed that she had a positive Pap smear and Patient #2 was informed his/her urine specimen was negative. Subsequent to Patient #1's diagnosis of suspicion for sarcoma, the patient consented to a hysterectomy based on the information provided and Patient #2 was not informed timely that s/he had malignant cells consistent with urethelial high grade carcinoma. The findings include:
    a. Patient #1 was a 41 year old and had a pap (papanicolaou) smear sent for cytology to the facility laboratory as part of a routine gynecological (GYN) exam on 7/7/17. The cytology results of the Pap smear were reported on 7/18/17 as single large malignant cells epithelial abnormality, difficult to classify, uncertain if this is primary or metastatic. Patient #1 was referred by MD #1 to MD #2 (GYN Oncologist) and endocervical curettes and biopsies of the cervix and endometrium were performed on 7/24/17 and were negative for malignancy.

       Review of MD #2's office note dated 8/1/17 identified that Patient #1 was informed of the cytology results, was very emotional and MD #2 recommended a hysterectomy. A CT scan of the abdomen and pelvis dated 8/1/17 identified a questionable mass in the uterus and recommended that an MRI be performed. The MRI dated 8/5/18 identified multiple uterine fibroids and a non-suspicious cyst of the right ovary.

       Tumor Board documentation dated 8/3/17 directed that the cytology slides from the Pap smear be reviewed again. MD #2's office note dated 8/7/17 identified that the pathologist reviewed the case, suspicion was sarcoma and the Tumor Board recommended a hysterectomy be performed as soon as possible.

       Patient #1's operative report dated 8/15/17 noted that a total hysterectomy with removal of the tubes and ovaries was performed by MD #2 per the patient's consent. The pathology reports from the intraoperative frozen sections (uterus, cervix, tubes and ovaries) and omentum biopsy dated 8/15/17 indicated negative for malignancy.

       Review of facility documentation and MD #2's office notes dated 8/28/17 identified that the pap smear slide and results of 7/7/18 were switched with the abnormal urine cytology slide. MD #2 and MD #5 apologized for the error and recommended hormone replacement therapy. Although Patient #1 consented to the surgical procedure performed on 8/15/17, the Patient was provided with inaccurate information (results from Patient #2's urine specimen) on which the consent was based and an unnecessary surgical procedure was performed.

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Interview with the Chief Medical Officer on 7/20/18 at 12:11 PM stated that a repeat pap smear should have been done when no endometrial cells were noted in the original cytology results reported on 7/18/17.

Interview with MD #5 (Chair of OB/GYN) on 7/24/18 at 9:48 AM identified that the mix up in the lab led to a cascade of events that resulted in a mistaken hysterectomy. MD #5 further stated that although the patient may have had problems in the future related to fibroids that is not a reason to perform a hysterectomy.

b. Patient #2 was a 66 year old and had a urology visit with MD #3 on 7/7/17 for BPH (benign prostatic hypertrophy with unspecified urinary tract symptoms. The cytology results of the urine specimen sent on 7/7/17 was reported as no malignant cells on 7/11/17. MD #3's undated follow-up entry identified that Patient #2 was informed that the lab results were within normal limits, will follow-up at next appointment. Review of the follow-up urology notes identified that Patient #2 was contacted on 8/18/17 and 8/21/17 that a repeat urine test was requested by MD #3. The urine cytology reported on 8/29/17 identified positive for malignant cells consistent with urethelial high grade carcinoma. MD #3's documentation for the urology visit dated 8/31/17 indicated that the abnormal lab results and the lab error for the 7/7/17 urine were reviewed with Patient #2 and the Patient was asked to get a follow-up CT scan. The visit note dated 8/31/17 further indicated that the Patient would have a cystoscopy within the next 2 weeks (by 9/14/17). Review of the Procedure note dated 10/24/17 identified that MD #3 performed a cystoscopy on Patient #2 and the Patient was to have a CT scan on 10/24/17.

Interview with MD #3 on 7/24/18 at 9:15 AM identified that it was not known until 8/29/17 that the Patient had bladder malignancy. A subsequent interview with MD #3 on 7/26/18 at 8:00 AM noted that if the first urine for cytology dated 7/7/17 had been reported as positive for malignancy on 7/11/17, he would have ordered that a repeat urine for cytology be performed to ensure accuracy as the Patient did not have hematuria.

Interview with MD #10 on 7/24/18 at 1:03 PM identified that after Patient #1's pathology reports obtained during the hysterectomy were negative, it was determined that slides were switched during processing on 7/10/17 directly affecting Patient #1 and Patient #2. MD #10 stated the other patients that had samples processed in the same tray were negative for malignancy and/or were insignificant.

Interview with MD #11 on 7/20/18 at 9:30 AM identified that although he was not employed when the incident occurred, he was made aware that the cytology prep technician incorrectly placed the tray of samples causing eight (8) of the twelve (12) samples to be flip flopped.

Review of facility documentation dated 8/21/17 identified that cytology specimens were switched at processing with a root cause analysis and investigation initiated. Interview with MD #8 on 7/24/18 at 10:08 AM stated a number of conditions led to the system error that have been corrected with a second staff member in the lab. Facility

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documentation demonstrated that separate performance of urine and GYN specimens and a double check specimen verification process was implemented on 8/23/17. This process was verified during the onsite visits.

Review of the Patient Rights and Responsibilities Policy identified the patient has a right to receive high quality care, had a right to be informed of personal health status and a right to receive information necessary to give informed consent prior to the initiation of certain procedures or treatments.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) and/or (i) General (6).

2. *Based on medical record review, review of facility policies, review of facility documentation, and interviews, the laboratory failed to ensure proper oversight for test systems developed and used to provide quality services and when problems are identified, assess the effectiveness of corrective action taken, including revision of policies and procedures; issuance of corrected reports and documentation of staff notification, and retraining in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements.

A. Review of facility documentation during the period of 11/23/15 and 8/22/17, the laboratory processed 1,564 SurePath urine cytology specimens. On 7/10/17, during specimen processing and slide preparation, the cytology prep technician loaded the slides incorrectly which resulted in the switching of 8 patient samples. This resulted in an incorrect positive GYN smear for Patient #1 and an incorrect negative urine cytology result for Patient #2. Urine and PAPs were switched because the tray was loaded backwards. During slide preparation.

Based on the aforementioned error, the facility initiated a Root Cause Analysis (RCA) Event: Cytology Specimen Mismatch, July 10, 2017, Date of RCA: August 28, 2017, Corrective Action Plan located in the hospital Performance Management department, revealed:

a) Root Cause: Processing urine and GYN specimens on the same slide tray.

b) Corrective Action Plan: "Perform all urine and GYN specimen processing separately.

i. GYN specimens will be processed at different times and on separate slide trays from the urine specimens.
ii. Will add a double check verification process prior to specimens running through the "Prep Stain" process. Verifier will check that the information (Accession # and the patient's name) on the centrifuge tubes matches the information on the corresponding slides (e.g. info on tube in slot 1 on the centrifuge tube holder matches info on slide in slot 1 on tray and so on.

iii. red marking placed on slide tray to indicate start for position 1."

c) 'Who/Time Frame Status Updates': Cyto Prep Tech will start 8/29/17.

d) Root Cause: Distractions i. "Tech having to answer phone calls, Assisting other staff with issues, leaving lab to assist with FNA ..."

e) Corrective Action Plan:

i. "Will educate administrative staff to screen phone calls and triage information ii. "Educate central processing staff on a designated where to leave specimens."

iii. "Institute STAR decal to act as a stop zone for interruptions when techs are in the midst of processing specimens. Lab staff will need to be educated on new process change."

f) 'Who/Time Frame Status Updates': Manager; education to start 8/29/17.

Although the facility developed a comprehensive plan to address the above issues, review of facility documentation with MD #11 on 7/20/18, failed to provide evidence that corrective measures were implemented and/or monitored.

B. Record review on 7/20/18 of an untitled excel spreadsheet received from the cytology manager revealed, "cytology specimens switched at processing. RCA investigation with RM 8/21/17," was the only thing written on it.

C. Record review on 7/20/18 of the laboratory's 'GYN Processing, Surepath Method' procedure revealed:

a) The facility failed to update the policy until 6/21/18 (11 months later) with the following: "Verification of proper positioning of tubes and slides is performed by a second individual and accession numbers are recorded and initials are placed on the GYN/Anal Surepath Tube/Slide Verification Monthly Sheet."

b) Although additional corrective actions of the red dot to the tray, statement of running GYN and non-GYN separately and the use of the STAR decal noted in the RCA, these actions were not added to the procedure.

D. Record review on 7/20/18 of the 'Protocol for Urine Preparation Using Surepath Liquid Based Technology' procedure revealed:

a) The facility failed to update the policy until 6/21/18 (11 months later) with the following: "Verification of proper positioning of tubes and slides is performed by a second individual and accession numbers are recorded and initials are placed on the NONGYN (Urine) Surepath Tube/Slide Verification Monthly Sheet."

b) Additional corrective actions of the red dot to the tray, statement of running GYN and

non-GYN separately and the use of the STAR decal noted in the RCA were not added to the procedure.

E. Record review on 7/20/18 of the laboratory staff training records failed to provide evidence of documentation that staff were notified and/or educated of the plan as outlined in the RCA:

a) Notification and staff retraining documentation was not available for 5 of 5 cytology personnel.

b) Documentation of the education of administrative staff, central processing staff, laboratory staff and the STAR Decal was not available.

F. Record review on 7/20/18 of the CoPath Specimen Search report revealed the first urine cytology specimen processed utilizing the Surepath CytoRich Clear Preservative was on 11/23/15. The facility failed to ensure an approved written procedure by the laboratory director was in place prior to the implementation. The first documented written procedure, 'Urine Cytology Prep using SurePath', was signed by MD #9 on 6/21/16 (7 months following the implementation of the procedure), and not the Laboratory Director in accordance with CLIA requirements effective on 6/21/16 (7 months later). The Laboratory Director approved the procedure on 11/17/17 (2 years after the implementation of the procedure).

In addition, the statement for proper loading of specimens and slides was not included in this procedure.

Interview with cytology prep tech #1 (CPT1) on 7/20/18 at 10:00 AM stated that handwritten notes from the training session with the manufacturer representative were first utilized while a written procedure was being worked on. The facility was unable to provide a manufacturer procedure for Urine Cytology Prep using SurePath.

Interview with the Manufacturer Application Specialist on 7/23/18 at 12 PM stated the facility must develop its own policy and procedures as non-GYN processing is not approved by the Federal Drug Administration.

G. Record review on 7/20/18 of the 'Quality Plan for Anatomic Pathology' procedure revealed:

a) "The quality program in Anatomic Pathology at Bridgeport Hospital covers surgical pathology, cytopathology and autopsy pathology."

b) "Reporting is designed to be presented at monthly meetings of the quality committee."

c) "Documentation of actions taken to correct any deficiencies detected by the quality

program is maintained along with other Quality reports in the minutes. The minutes are stored in the office of the Manager of the Laboratory. Follow-up review ensures that the deficiencies, once detected, are corrected."

d) "Quality program in cytopathology: see separate Cytopathology Manual."

Interview with MD #11 on 7/20/18, failed to provide documentation of actions taken to address the specimen mismatch.

H. Record review on 7/20/18 of the laboratory's 'Quality Assurance Minutes Date September 7, 2017' cytology section revealed, "Everyone in cytology will be having competency review per manager." Documentation of follow-up review was not available.

I. Record review on 7/20/18 of the 'Quality Assurance for Gynecologic Cytology' policy Section IV Cytologic/Histologic Correlation revealed:

a) "A statement is included in the surgical final diagnosis regarding correlation, lack of correlation....Further categorization (monthly) is also documented which segregates agreement, disagreements, and unable for review types. This enables us to pick up sampling, screening interpretive, and misclassification errors. Such findings are so noted in the quality improvement report and presented at the monthly QA conference."

b) Preanalytical quality assessment was not addressed.

J. Review of the 'Quality Assurance Program for Gynecologic Cytology' procedure revealed: Section XIIIa Corrected Reports: "If there is a change in diagnosis an amended report will be issued stating reason for change in diagnosis." Record review on 7/20/18 of the final GYN cytology report on Patient #1 revealed a corrected report was not issued at time of discovery of sample mismatch in August 2017. Report was amended/corrected on 7/3/18.

K. The laboratory failed to follow manufacturer instructions for proper orientation of samples based on the "PrepStain Slide Processor 780-06181-00 Rev B Operator's manual.

a) Chapter 4 PreProcessing Steps, Chain of custody section states:

i. "In order to maintain chain of custody of test samples, all specimen vials, centrifuge tubes, and glass slides are loaded in their respective racks front to back and left to right."

ii. "Warning: Tubes in centrifuge racks must be carefully oriented with matching slide racks. Correct placement of labeled tubes with correspondingly labeled slides is essential and must be verified by the operator in order to prevent

sample mix-ups."

Record review on 7/20/18 of the 'GYN Processing Surepath' procedure, effective Feb. 2006 failed to include a statement regarding the proper orientation of samples throughout processing and staining.

L. The laboratory failed to follow manufacturer instructions for non-GYN samples based on the 'PrepStain Slide Processor 780-06181-00 Rev B Operator' manual Appendix C, 'Non-GYN Slide Processing' details the use of the PrepStain Non-GYN application to process Non-GYN specimen slides.

Record review on 7/20/18 of the 'Protocol for Urine Preparation using Surepath Liquid Based Technology' procedure revealed, urine samples are run on the "PrepStain per protocol using gynecological software." This contradicts manufacturer directions.

M. Record review on 7/20/18 of the 'Bridgeport Hospital Laboratory 2018 Quality Assurance and Process Improvement Plan and 2017 Evaluation' revealed the following:

a) Laboratory initiatives are reported to the Ancillary Services Vice President and taken to the Quality meeting and the Board of Directors as part of the Ancillary Quality report.

b) Process Improvement (PI) is defined as an effort to insure that test results generated by the laboratory are integrated into patient care so that a positive clinical outcome is achieved for the patient.

c) The goal of the total quality improvement program is to provide an organized approach for identifying appropriate areas of concern within the total test process, developing strategies for intervention when necessary, measuring the result of corrective actions taken, to be sure that improvement is maintained over time, and emphasizing continuous improvement.

d) 2018 Plan indicator changes did not include the cytology section.

e) Quality Improvement Activities summary for 2017 did not reference changes implemented for the specimen processing of cytology specimens or monitoring of corrective action taken to prevent recurrence of specimen integrity issues.

Staff interview with the Ambulatory Services Vice President (ASVP) on 7/20/18 at 9:15 AM revealed the ASVP was new to this position in January 2018; ASVP stated he/she was not aware of any initiative reports from the laboratory in 2018 to date. Documentation was not available.

Staff interview with the MD #11 on 7/20/18 at 9:30 AM stated he was working on quality assurance report but has not been submitted yet for 2018. In addition, MD #11

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stated he reports quarterly to the Med Exec Committee and the report from the laboratory is test volumes and new/ongoing business model; no quality assurance is reported.

The facility laboratory failed to provide evidence that the RCA was fully implemented and/or failed to follow their own procedures.